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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

(SAN FRANCISCO DIVISION)

STATE OF CALIFORNIA ex rel.) CASE NUMBER 07-cv-04911-CRB
JAYDEEN VICENTE and JAYDEEN)
VICENTE Individually,) PLAINTIFF-RELATOR JAYDEEN
Plaintiffs,) VICENTE'S MEMORANDUM IN
vs.) OPPOSITION TO DEFENDANT ELI LILLY
ELI LILLY AND COMPANY,) AND COMPANY'S MOTION TO DISMISS
Defendant.) UNDER RULES 12(b)1, 12(b)(6) AND 9(b)
Date: December 7, 2007
Time: 10:00 a.m.
Courtroom: 8, 19th Floor
Honorable Charles R. Breyer

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I. INTRODUCTION

Eli Lilly & Company's ("Lilly") Motion To Dismiss ("Motion") is based on inapplicable government knowledge defenses and mischaracterizations of the Federal Rules of Civil Procedure and the California False Claims Act ("CaFCA"). It should be denied in all respects.

II. STATEMENT OF FACTS

The Complaint and Exhibits¹ thereto (all but 2 of which Lilly has conceded to be non-public), Relator Jaydeen Vicente (“Relator” or “Relator Vicente”), a Lilly employee for 3 years, exposes Lilly’s scheme to unlawfully expand Zyprexa’s limited on-label market by creating a Zyprexa sales division to promote Zyprexa solely to Long Term Care (“LTC”) facilities and the pharmacies that supply their prescription needs. Pursuant to Lilly’s LTC business plan, Lilly’s 160 LTC sales representatives did not market the drug for any on-label or otherwise approved use.

Instead, the LTC sales force was exhaustively trained by Lilly to aggressively promote its potent, dangerous atypical antipsychotic drug designed and FDA-approved to treat adult schizophrenia and bi-polar disorder to LTC physicians and pharmacies that supply LTC patients prescription drugs as safe and effective to treat elderly LTC facility residents' symptoms such as anxiety, aggression, agitation, insomnia, and disruptive behaviors. Zyprexa has not received (nor has Lilly sought) FDA approval to treat any of these symptoms, nor are they supported by the medical compendia DRUGDEX, the American Hospital Formulary Service Drug Information or the United States Pharmacopeia-Drug Information. Nor had the FDA approved or medical compendia

¹ Relator's Complaint and its Exhibits are attached to the Declaration of Jeanette Haggas ("Decl."), filed concurrently herewith. For the Court's convenience, the Complaint's Exhibits are referenced in this Memorandum by their Complaint Exhibit identifying letter.

1 supported Zyprexa as a safe or effective drug to treat the elderly. To the contrary,
 2 Zyprexa's label contains a FDA-mandated "black box warning" stating the drug increases
 3 the risk of death in the elderly population. Further, the cornerstone of Lilly's off-label
 4 LTC marketing message was to promote the drug for any benefit to the *patient*, but
 5 instead for the benefit of the LTC patients' caregivers because the drug's sedative
 6 properties act as a chemical restraint reducing caregiver time and effort.

7 Relator's Complaint also discloses the LTC sales division's astounding financial
 8 success, the Lilly personnel who created and implemented the mendacious LTC
 9 marketing scheme, and the Lilly LTC salespersons who delivered Lilly's unlawful off-
 10 label message. She has identified key customers Lilly targeted to pitch Zyprexa off-label
 11 sales and the physicians who accepted Lilly's kickback payments. She also exposed
 12 Lilly's LTC-specific tools, props, training guides, business plan, and Lilly's Peer to Peer
 13 Implementation guide revealing Lilly's kickback scheme.

14 III. STATEMENT OF THE CASE

15 On May 11, 2007, Relator commenced this *qui tam* action individually and on
 16 behalf of the State of California to recover damages and civil penalties exclusively under
 17 the California False Claims Act and the California Business and Profession Code.

18 IV. ARGUMENT

19 A. THE PUBLIC DISCLOSURE BAR IS INAPPLICABLE.

20 Relator's allegations of false claims submissions caused by Lilly's LTC sales
 21 division are not based upon, derived from, or substantially similar to the newspaper
 22 reports of Lilly's marketing misconduct of causing injuries to tens of thousands of
 23 patients through its failure to disclose the drug's dangerous side effects;² rather, they arise

24
 25 ² For example, Lilly cites to a Hersh & Hersh press release. Motion at 8 n.6. This press release
 26 pertained exclusively to *personal injury* lawsuits seeking individual damages. The press release disclosed
 nothing pertaining to the allegations in this case.

27 ³ Lilly agrees federal decisions are persuasive on the meaning of the CaFCA. Motion at 15 n.9.

1 solely from her personal and direct knowledge gained during her 3 year employment as a
2 Lilly LTC sales representative. Further, the information Lilly reported about
3 investigations into Lilly's "marketing practices" in connection with its defense of
4 numerous personal injury lawsuits discloses nothing like the nature of the fraud alleged
5 here involving Lilly's LTC sales division.

6 Lilly's admissions in its Motion To Seal defeat its public disclosure argument
7 here. Lilly's *Ex Parte* Motion to Place Documents Under Seal ("Mot. To Seal"), Dckt.
8 No. 18; *see* Civ. Local R. 79-5. Lilly asserted 12 out of 14 Exhibits are "confidential,
9 sensitive documents" and "commercial information, product planning, and employee
10 training techniques," "the disclosure of which would harm Lilly by 'by revealing its trade
11 secrets, confidential preliminary research, and merchandising techniques.'" Mot. To Seal
12 ¶¶12-13; 19; *see* ¶¶9, 20. It follows that Relator's exhibits, by definition, are not in the
13 public domain. Lilly concedes further by continuing, "[i]n particular, these exhibits
14 provide information regarding Lilly's Zyprexa marketing strategies, information which
15 its competitors would not otherwise be able to obtain." Mot. To Seal ¶18.

16 Applying the public disclosure bar here contradicts legislative intent. Many
17 courts, including *City of Hawthorne ex rel. Wohlner v. H&C Disposal*, 109 Cal. App. 4th
18 1668 (2003), held that the CaFCA is designed to supplement governmental efforts to
19 identify and prosecute fraudulent claims made against state and local governmental
20 entities by authorizing private parties to bring suit on behalf of the government, with the
21 ultimate purpose of protecting the public. *Id.* at 1677. CaFCA is to be "construed
22 broadly *so as to give the widest possible coverage and effect to its prohibitions and*
23 *remedies.*" *Id.* (emphasis added). The public disclosure jurisdictional bar is designed to
24 thwart opportunistic *qui tam* actions by "claim mongers" who take advantage of public
25 information without contributing to the exposure of the fraud and therefore should be
26 applied "only as necessary for that end." *City of Hawthorne*, 109 Cal. App. 4th at 1683.

1 Further, courts must analyze the jurisdictional status of each reasonably discrete
 2 claim of fraud in a *qui tam* action. *U.S. ex rel. Louanne Booth v. Sun Healthcare Group,*
 3 *Inc.*, 496 F.3d 1169 (10th Cir. 2007). Hence, to the extent one claim of fraud under the
 4 CaFCA is barred by a public disclosure, the other claims not publicly disclosed survive.

5 The purported public disclosures in this case are also analogous to those in *U.S. ex*
 6 *rel. Found. Aiding the Elderly v. Horizon*, 265 F.3d 1011 (9th Cir. 2001);³ *accord, City of*
 7 *Hawthorne*, 109 Cal. App. 4th at 1684-85. There, one predecessor lawsuit alleged
 8 “defendants generally misrepresented to them the level of care provided by the particular
 9 nursing facility.” *Found. Aiding the Elderly*, 265 F.3d at 1015. The *qui tam* lawsuit, in
 10 contrast, alleged that the defendants “misrepresented the level of care to the government
 11 and received payment for that alleged substandard care.” *Id.* at 1015. Accordingly, the
 12 Ninth Circuit found the public disclosure bar did not apply because the two prior lawsuits
 13 had revealed instances of fraud, but not the particular fraudulent conduct at issue in the
 14 subsequently filed *qui tam* action. *Id.* at 1016.

15 As in *Foundation Aiding the Elderly* and *City of Hawthorne*, Relator’s *qui tam*
 16 lawsuit is distinct from the conduct described in the so-called public disclosures. The so-
 17 called public disclosures upon which Lilly relies revealed general instances of Lilly’s
 18 fraudulent marketing of Zyprexa, mostly to primary care physicians for the treatment of
 19 an entirely different patient population as well as report on personal injuries suffered for
 20 which plaintiffs in personal injury suits seek individual damages. Those do not rest upon
 21 a complex scheme to defraud the State of California through the development of a LTC
 22 marketing machine. Also, as *Foundation Aiding the Elderly* and *City of Hawthorne*
 23 instruct, the mere existence of prior lawsuits does not constitute a public disclosure where
 24 the type of fraud alleged in a subsequent *qui tam* action has not been revealed.

25 The court in *City of Hawthorne* cautions against accepting Lilly’s argument,
 26 which would result in immunizing the defendant from liability in *qui tam* actions. *Id.*,
 27

1 109 Cal. App. 4th at 1684-85. The Complaint demonstrates the purported public
 2 disclosures do not reveal the particular fraudulent conduct appearing in Relator Vicente's
 3 Complaint. Consequently, Lilly's broad application of the public disclosure bar fails.

4 **B. RELATOR VICENTE STATES VALID CLAIMS FOR UNFAIR
 5 COMPETITION AND FALSE ADVERTISING.**

6 **1. As A *Qui Tam* Plaintiff, Relator Vicente "Stands In The Shoes Of The
 Government" To Assert Claims On Its Behalf.**

7 Relator Vicente represents the State in this *qui tam* action. A *qui tam* action is
 8 one that "allows a private person to sue for a penalty, part of which the government or
 9 some specified public institution will receive." Blacks Law Dict. *qui tam action* (8th ed.
 10 2007). The *qui tam* plaintiff "stands in the shoes of the government" to allege claims on
 11 its behalf. *Wells v. One 2 One Learning Found.*, 39 Cal. 4th 1164, 1214 (2006),
 12 remanded on other grounds, No. C042504, 2006 WL 3354022 (Nov 20, 2006); Cal.
 13 Gov't Code §12652(c)(1), (f)(1). Further, *qui tam* actions effect "a partial assignment of
 14 the Government's damages claim to the relator," which is an adequate basis for standing
 15 to assert the injury in fact suffered by the assignor." *Vermont Agency of Natural
 Resources v. U.S. ex rel. Stevens*, 529 U.S. 765 (2000). Here, Relator Vicente alleges
 16 claims on behalf of the State to recapture the money that Lilly defrauded from it.
 17 Whether the State is a party in this action does not defeat Relator's action for damages
 18 and any award Relator receives will escheat to the State. Thus, Relator has standing to
 19 pursue the unfair competition claims as a *qui tam* plaintiff.

20 **2. Relator Vicente Has Standing Under Business And Profession
 21 Sections 17203, 17204 And 17535.**

22 "Any person may pursue representative claims or relief on behalf of others . . . if
 23 the claimant meets the standing requirements of Section 17204 and complies with Section
 24 382 of the Code of Civil Procedure." Cal. Bus. & Prof. Code §17203. Both Section
 25

26 ⁴ Lilly cites to *Grayson*, which did not address the merits of whether the plaintiff sufficiently
 27 alleged an injury. *State ex rel. Grayson v. Pac. Bell Tel. Co.*, 142 Cal. App. 4th 741, 757-58 (2006). There,
 the plaintiff only opposed Proposition 64's application to pending lawsuits.

1 17204 and 17535 provide for a private right of action for any relief by “any person who
 2 has suffered injury in fact and has lost money or property as a result of such unfair
 3 competition.” Cal. Bus. & Prof. Code §17204, *as modified* by Proposition 64; Cal. Bus.
 4 & Prof. Code §17535. Thus, the statute intends to encourage private actions when an
 5 unresponsive government refuses to prosecute for the protection of the California
 6 consumers: exactly the situation that Relator Vicente seeks to remedy.

7 Relator Vicente suffered injury when the government paid Lilly for falsified
 8 submissions for unlawful and off-label Zyprexa sales. *See White v. Trans Union, LLC*,
 9 462 F. Supp. 2d 1079, 1083-84 (C.D. Cal. 2006). In *White*, the court held that
 10 TransUnion’s inaccurate credit reports for the plaintiffs’ “due and owing” debts
 11 constituted a sufficient injury to confer standing. *Id.* (“Plaintiffs do satisfy the UCL’s
 12 standing requirements because they have alleged injury-in-fact and a loss of income as a
 13 result of unlawful competition. . . . This is all that the statute requires.”).⁴

14 Relator lost considerable money due to Lilly’s deceitful claims for reimbursement
 15 from the California Medicaid program. Specifically, part of her paycheck was withheld
 16 for California Medicaid. Lilly then fraudulently seized that money by submitting false
 17 claims for reimbursement. It is this transitive relationship between Vicente’s taxes and
 18 Lilly’s receipt of unearned reimbursements that confers standing. Decl. Exh. 1
 19 (Complaint) ¶29 (Medicaid is government-funded), ¶17 (Plaintiff was employed).

20 This action also meets the requirements of Section 382: (1) an “ascertainable
 21 class” of numerous parties and (2) “community of interest in the questions of fact and law
 22 involved.” Cal. Code Civ. Proc. §382. Relator seeks relief on behalf of the State to
 23 recapture tax dollars that were improperly expended due to Lilly’s fraud on the
 24 government. *See generally*, Decl. Exh. 1 (Complaint). Thus, this action is brought on
 25 behalf of all California taxpayers whose money funded the State Medicaid program.
 26 Also, each taxpayer has virtually identical claims against Lilly for defrauding the State
 27

1 out of millions of dollars by submitting falsified reimbursement claims to California's
 2 Medicaid program for off-label Zyprexa use. Relator, as a *qui tam* plaintiff, is capable of
 3 vigorously and tenaciously protecting class interests and acting as a fiduciary for both the
 4 class and the State of California. *See generally*, Decl. Exh. 1 (Complaint).

5 **3. Relator Also Has Taxpayer Standing.**

6 Taxpayers may enjoin a government's wasteful expenditures of tax money. Cal.
 7 Code Civ. Proc. §526(a). This statute is liberally construed and its purpose is to enable
 8 the public to challenge government action "which would otherwise go unchallenged . . .
 9 because of the standing requirement." *Blair v. Pitchess*, 5 Cal. 3d 258, 267-68 (1971).

10 Importantly, a taxpayer action can enforce the government's duty to collect funds
 11 due the State. *Vasquez v. State of California*, 105 Cal. App. 4th 849, 845-55 (2003);
 12 *accord, Waste Mgmt. of Alameda County, Inc. v. County of Alameda*, 79 Cal. App. 4th
 13 1223, 1240 (2000); Cal. Code Civ. Proc. §526(a). This is precisely what Relator Vicente
 14 is doing. Relator suffered an injury traceable to Lilly's unlawful conduct that the Court
 15 can redress. Relator regularly cited specific facts and reasons to believe that the State
 16 wastefully reimbursed and continues to reimburse Lilly for falsified submissions for
 17 unlawful Zyprexa sales. *See, e.g.*, Decl. Exh. 1 (Complaint) ¶¶1-3, ¶9, ¶11. Moreover,
 18 the State declined to intervene, leaving Relator Vicente the sole advocate for the State's
 19 right to reimbursement of the money Lilly defrauded the State.

20 **C. THE COMPLAINT SATISFIES FED. R. CIV. PROC. 9(b).**

21 **1. Federal Rule Civil Procedure 9(b).**

22 Rule 9(b) of the Federal Rules of Civil Procedure is satisfied if the circumstances
 23 constituting fraud are identified "so that the defendant can prepare an adequate answer

1 from its allegations.” *Moore v. Kayport Package Express, Inc.*, 885 F 2d 531, 540 (9th
 2 Cir. 1989) (emphasis added).

3 Lilly does not argue that it cannot in good faith respond to Relator’s Complaint.
 4 Further, Relator’s Complaint contains an abundance of facts specific to the case. *See*
 5 *generally* Decl. Exh. 1 (Complaint). Relator conducted a thorough investigation into the
 6 facts underlying the causes of action and Relator has pled the fraud causes of action with
 7 the particularity required by Rule 9. Specifically, Relator alleged facts regarding the
 8 “who”, “what”, “where”, “when” and even “how” Lilly defrauded the State. *See* Part
 9 C.2, *infra*; Decl. Exh. 1 (Complaint).

10 Moreover, certain circumstances, present here, permit the relaxation of Rule
 11 9(b)’s requirements. When the facts concerning a plaintiff’s allegations of fraud are
 12 within the defendant’s control, less specificity of pleading is required pending discovery.
 13 Where allegations are “complex and far-reaching, pleading every instance of fraud would
 14 be extremely ungainly, if not impossible.” *U.S. ex rel. Franklin v. Parke-Davis, Div. of*
 15 *Warner-Lambert Co.*, 147 F. Supp. 2d 39, 49 (D. Mass. 2001) (“*Franklin I*”).

16 Relator Vicente has adequately alleged the elements of a CaFCA claim based
 17 exclusively upon her personal knowledge and “confidential” Lilly documents (including
 18 DURs) she received during her employment. Lilly attempts to create a technical hurdle
 19 that makes pleading fraud in complex cases impossible. Indeed, a plaintiff cannot
 20 provide the actual claims, the specific dates and amounts of those claims, especially
 21 where the plaintiff has left employment with Defendant, and was stripped of the
 22 documents that prove her case. *See, e.g.*, Mot. To Seal ¶¶9-11.

23 Relator’s Complaint meets Rule 9 by alleging the false statements made (Lilly’s
 24 false reimbursement claims) were fraudulent because Lilly knew, based on its intentional
 25 off-label Zyprexa marketing scheme, that it was not entitled to reimbursements from the
 26 State Medicaid program. *See Warshaw v. Xoma*, 74 F.3d 955, 960 (9th Cir. 1996)

(finding plaintiffs met Rule 9 by alleging defendants had knowledge their statements were false). Thus, where a relator pleads a complex fraudulent scheme with particularity and provides examples of specific false claims submitted to the government pursuant to that scheme, the relator may proceed to discovery on the entire fraudulent scheme. Accordingly, Relator Vicente's Complaint withstands dismissal under Rule 9(b).

2. The Factual Allegations In The Complaint And Attached Exhibits Provide Sufficient Specificity To Withstand Lilly's Dismissal Attempt.

Lilly's argument that Relator has not identified any claim for payment or government reimbursement is inaccurate. Motion at 16. A complaint satisfies Rule 9(b) with regard to ineligible purchases of a drug by Medicaid even without identifying a single claim, provided it details the framework of fraud and identifies the individuals, locations, the precise statements that caused the submission of false claims, and times. *Franklin I*, 147 F. Supp. 2d at 49.⁵ Relator Vicente's Complaint therefore does not fail because she lacked access to the documents supporting her claims due to her position as a LTC sales representative. Moreover, her claims are properly alleged and presumed true at this stage in litigation. Upon Vicente's resignation, Lilly stripped her of the records that would arm her claims. Thus, a dismissal here would reward Lilly's deceit.

Relator adequately alleged fraud with particularity under Rule 9(b). Relator is not required to attach Lilly's false Medicaid claims; she meets the Rule 9(b) standard through her particularized pleadings. Specifically, Relator alleged that Lilly informed her that her sales efforts increased Zyprexa LTC sales. Decl. Exh. 1 (Complaint) ¶¶10, Exh. H at 1 (Rankings of top Lilly LTC sales reps); see Decl. Exh. 2 at 1 (Lilly's LTC "Best Practices Newsletter" trumpeting its extremely successful sales).

⁵ Lilly's analogy to *County of Santa Clara v. Astra, USA, Inc.*, 428 F. Supp. 2d 1029 (N.D. Cal. 2006), is inapposite. *Santa Clara* involved a distinct false claim theory, drug overpricing, and the County failed to identify the basic elements of the claim, despite having the data to plead the claim with specificity. *Id.* That is not the case here.

1 Lilly does not dispute that at all times relevant to this action, Zyprexa was FDA-
2 approved to treat adults for schizophrenia, acute bipolar mania and for the maintenance
3 treatment in bipolar disorder, among other mood disorders. Lilly also agrees that LTC
4 facilities house a disproportionately large population of Medicaid beneficiaries and those
5 beneficiaries rely upon those programs to shoulder the bulk of the cost of drugs
6 prescribed to them.

7 Relator also satisfied the “who” element. The Complaint and Exhibits identify
8 key LTC personnel, the management personnel responsible for devising the LTC
9 marketing and business plan, and individuals who instructed LTC sales representatives to
10 fraudulently promote off-label use of Zyprexa. Decl. 1 (Complaint) at Exh. H. The
11 Complaint and its exhibits identify by name and territory Lilly’s LTC sales
12 representatives who unlawfully promoted Zyprexa off-label use pursuant to Lilly’s LTC
13 business plan. Relator further identified physicians who accepted kickbacks to influence
14 their prescribing behavior and the identities of closed-end pharmacies who were detailed,
15 including NeighborCare, Relator Vicente’s “biggest client.” Decl. Exh. 1 (Complaint) at
16 Exh. C at 5.

17 The “when” of the complaint is identified as August 1999 (pursuant to Lilly
18 documentation as to the existence of the LTC sales division) through at least June 2003.
19 Decl. Exh. 1 (Complaint) ¶¶73 (citing Exh. A), 186, 225, 232. The Complaint further
20 alleges that the actionable conduct continued beyond her employment, given the LTC
21 sales division remained in full swing after Relator’s voluntary termination. *Id.*

22 Relator satisfied the “what” by alleging (1) Lilly’s conduct resulted in the
23 submission of tens of thousands of Zyprexa prescriptions that were not eligible for
24 reimbursement under Medicaid because they were prescribed for off-label uses not
25 approved by medical compendia and (2) alleging with particularity the federal regulations
26

1 rendering them ineligible for reimbursement. Decl. Exh. 1 (Complaint) ¶¶9, 11, 15, 37-
 2 51, 56-58, 63-64, 70, 85, 90, 96, 98, 100, 105, 179-86, 202-11.
 3

4 Relator sufficiently pled the “how” by describing Lilly’s LTC marketing
 5 campaign in which kickbacks and unlawful and deceptive marketing strategies, tools, and
 6 sales aids were used to increase usage of Zyprexa for off-label, non-medically accepted
 7 uses. Decl. Exh. 1 (Complaint) ¶¶6; 20-21, 101-03, 105-34, 152-66, 196-201.

8 Relator has set forth with specificity the framework of the fraud, the key players,
 9 and a solid factual basis for alleging false claims were submitted. This is sufficient to
 10 withstand a Rule 9(b) motion to dismiss, particularly where Relator cannot identify
 11 specific false claims because the Relator does not have access to such patient-specific
 12 information. *See, e.g., Franklin I*, 147 F. Supp. at 48-49.

13 **3. Relator’s Claims For Causing False Claims To Be Submitted Is**
 14 **Legally Valid.**

15 Relator need only show that Lilly “caused to be submitted” a false claim, not that
 16 the claim itself was “untrue”. CaFCA Section 12650(a)(1). However, Lilly seeks to
 17 require Relator to prove both that (1) Lilly “caused to be submitted” false claim *and* (2)
 18 that the claim was “untrue”. Motion at 18. The plain language of the statute does not
 19 require this. In fact, courts expressly reject a “double falsity” requirement. *See U.S. ex*
 20 *rel Franklin v. Parke Davis*, No. 96-11651, 2003 WL 22048255 (D. Mass. Aug. 22,
 21 2003) (“*Franklin II*”) (“because Relator has not limited his FCA claim to §3729(a)(2), he
 22 need not show two falsehoods to prevail Under §3729(a)(1), the only issue is
 23 whether Parke-Davis ‘caused to be presented’ a false claim and §3729 does not require
 24 that the ‘cause’ be fraudulent or otherwise independently unlawful”). Indeed, the FCA
 25 and the virtually identical CaFCA apply to “all fraudulent attempts to cause the
 26 Government to pay out sums of money.” *Franklin I*, 147 F. Supp. 2d at 50-51.

Here, Relator alleged liability under CaFCA Section 12650(a)(1) for submitting false reimbursement claims to the State's Medicaid program. Like the plaintiff in *Franklin II*, she does not limit her allegations to a Section 12650(a)(2). Rather, her claims under Section 12650(a)(2) are stated in the alternative. Decl. Exh. 1 (Complaint) at ¶¶6, 106-08, 152-66, 192-201, 202-11, 228-33, Exhs. K, J, I, L, and M. Specifically, Relator alleged that Lilly's kickbacks caused ineligible claims to have been submitted containing a false statement: that the claims complied with all laws, including the federal Anti-Kickback Act. Decl. Exh. 1 (Complaint) ¶¶204-09, Exhs. J-M.

4. The Zyprexa And Zyprexa ZYDIS Claims Submitted To Medicaid For Reimbursement Are False Claims.

Relator Vicente alleges that Medicaid does not cover off-label uses of prescription drugs that are not prescribed for a medically-accepted indication. “Off-label” is defined as prescribing a drug for a condition not approved by the FDA (the drug’s “indication”), treating the indicated condition at a different dose or frequency than specified in the label, or treating a different patient population (*e.g.*, treating the elderly with a drug approved to treat adults). A “medically accepted indication” is defined as use that is approved by the FDCA or by the following medical compendia - the American Hospital Formulary System, the United States Pharmacopeia Drug Information and DRUGDEX. Unless an off-label use is supported by these compendia, an off-label prescription for that drug is not eligible for reimbursement under Medicaid.

Lilly ignores Relator's abundance of factual allegations that "Lilly devised, and successfully implemented through its divisions of Zyprexa sales representatives, a marketing campaign calculated to increase physicians' off-label use of Zyprexa within the State to treat symptoms, mood disorders and patients within age demographics for which the drug has not received FDA approval, nor which has been supported by the above referenced medical compendia. Decl. Exh. 1 (Complaint) at ¶¶2, 5, 29-70. Taking

1 these factual allegations to be true, and drawing all inference in favor of the plaintiff,
 2 Relator Vicente has stated a legally valid claim under the CaFCA.

3
 4 Lilly requests this Court resolve an unripe factual dispute by paraphrasing the
 5 DRUGDEX compendia as stating Zyprexa is “[e]ffective in low dose’ for dementia.”
 6 Motion at 19. Relator’s allegations of ineligible claims that Lilly submitted far exceeded
 7 dementia patients and Lilly LTC sales division aggressively hounded LTC physicians to
 8 increase Zyprexa dosages to increase revenue. Decl. Exh. 2 (LTC Best Practices
 9 Newsletter) (“The following are examples of how one may communicate the benefits of a
 10 patient being on Zyprexa 5mg versus settling with 2.5mg); Decl. Exh. 1 (Complaint) at
 11 Exh. B.

12 Lilly’s argument concerning physicians’ ability to prescribe drugs off-label is
 13 equally unavailing and irrelevant to the Medicare and Medicaid regulations restricting
 14 off-label reimbursements. At issue here is Relator’s well-pleaded factual allegations that
 15 Lilly submitted false, ineligible claims to Medicaid.

16 **5. Lilly’s Materiality Argument Is Facially Baseless.**

17 The gravamen of Lilly’s Motion is that Relator did not allege “any” false
 18 statements material to the reimbursement decision. Motion at 19. Lilly relies on a blank
 19 claims form as proof that “the diagnosis, and consequently the on-label or off-label nature
 20 of the prescription, was immaterial to the State, since it made [inclusion of diagnosis
 21 information] optional.” Motion at 19. But, this is a factual issue improper of a motion to
 22 dismiss. *See, e.g., Franklin II*, 2003 WL 22048255, at *4 (“[Defendant] raises a factual
 23 argument that ‘Medicaid reimbursement claim forms for prescription drugs do not require
 24 the claimant to list the indication for which the drug is being prescribed.’”).

25 Assuming, *arguendo*, materiality is an element of a CaFCA claim, Lilly has
 26 explicitly conceded that whether a prescription is off-label is pertinent to a

1 reimbursement decision. Motion at 17-19. Further, Lilly overlooks that the Zyprexa
2 reimbursement claims were false because the underlying diagnosis was not an “medically
3 indicated use,” and the prescriptions were written for elderly patients for whom Zyprexa
4 is not FDA approved. Relator alleged Lilly submitted claims through its Anti-kickback
5 violations, which indisputably meets the materiality requirement.

6 **6. The Submission Of False Claims Was The Foreseeable And Intended
7 End Result Of Lilly's Conduct.**

8 Lilly's reliance upon the learned intermediary doctrine fails. Causation exists
9 where it is foreseeable that a drug manufacturer's off-label marketing efforts would lead
10 to off-label prescriptions and the subsequent submission of claims to government
11 healthcare programs. *Franklin I*, 147 F. Supp. 2d at 52-53 (“the participation of doctors
12 and pharmacists in the submission of false Medicaid claims was not only foreseeable, it
13 was an intended consequence of the alleged scheme of fraud.”).

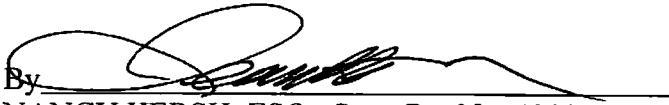
14 Lilly's LTC conduct (which specifically targeted a discrete patient demographic
15 that Lilly knew is disproportionately comprised of Medicaid beneficiaries) includes: LTC
16 marketing efforts; kickback payments; targeting of Tier 1 doctors through pharmacy
17 generated DURS; accompanying LTC physicians during rounds at nursing homes and
18 skilled nursing facilities; using slick sales pitches, slogans, detail aids, and manipulated
19 Lilly studies of geriatrics; appealing to caregivers through the chemical restraint sales
20 pitch; and detailing closed end pharmacies and their consulting physicians who assist
21 LTC facility physicians in making prescribing decisions. Indeed, Lilly's plan was to
22 increase unlawfully Zyprexa sales for elderly residents of LTC facilities. *See generally*,
23 Decl. Exh. 1 (Complaint). Importantly, Lilly's motion does not dispute that there was an
24 LTC sales force or that the purpose of that sales force was to promote the off label use of
25 the drug on a highly Medicaid dependent population.

26 When all reasonable inferences from the well-pleaded facts are drawn in favor of
27

1 the Relator (*see, e.g.*, Decl. Exh. 1 (Complaint) ¶¶2, 53-58, 64, 80-84, 101, 102-03, 110-
2 113-15 (citing Exh. N), 117-18, 123-25, 127, 216-19, 221-22), the participation of
3
4 doctors and pharmacists in the submission of false Medicaid claims was not only
5 foreseeable, it was an intended consequence of Lilly's scheme of fraud.
6
7

V. CONCLUSION

8 For the reasons stated above, Lilly's Motion To Dismiss should be denied. In the
9 alternative, Relator Vicente requests that she be granted leave to amend the Complaint.
10
11 DATED: November 16, 2007.

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14
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